AMERICAN JOURNAL OF INDUSTRIAL MEDICINE 37:142–157 (2000)

Medical Evaluation for Respirator Use

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The purpose of a respirator is to prevent the inhalation of harmful airborne substances or to provide a source of respirable air when breathing in oxygen-deficient atmospheres. For a physician to recommend the use of respirator, general background information on respiratory-protective devices is required. The first part of this clinical practice review describes the general aspects of industrial hygiene, respirators and a respirator-certification program. The second part addresses matters related to medical certification for respirator use.

Medical certification for respirators is an important part of the activities of the occupational physician. To determine whether a worker is able to tolerate the added strain of a respiratory protective device is a complex process in which factors such as fitness for work, health of the individual, characteristics of the work itself, and the properties, type, and requirements of the respiratory protective device, have to be considered. Medical certification is of utmost importance for respirator use, and it should be viewed as an element in a comprehensive respiratory protection program. A comprehensive program is the key element in affording the workers' effective respiratory protection once the initial steps of the hierarchy of methods of hazard control have proved insufficient or infeasible. As a result, the need for the industrial hygiene/safety officer, the worker, the employer and the medical professional to work as a team is much more than in any other field of occupational medicine—a necessary requirement for making the right decision. Am. J. Ind. Med. 37:142–157, 2000. © *2000 Wiley-Liss, Inc.*

KEY WORDS: respirators; occupational; medicine; clinical practice review; prevention; public health

OVERVIEW

The purpose of a respirator is to prevent the inhalation of harmful airborne substances or to provide a source of respirable air when breathing in oxygen-deficient atmospheres. Functionally, a respirator is designed as an enclosure which covers the nose and mouth or the entire face or head.

In order for a physician to recommend the use of a respirator, background information on respiratory-protective devices is required. For most people who are fit to do the job, there is usually a respirator model which will fit their needs. The first part of this clinical practice review will cover general aspects of industrial hygiene, respirators, and a respirator-certification program. The second part will address matters related to medical certification for respirator use.

The decision to use respirators to protect workers from workplace exposures should be based on a thorough understanding of the *hierarchy of methods for hazard control*. Once inhalation hazards have been identified and

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Contract grant sponsor: New York State Department of Health; Contract grant sponsor: NIEHS Center; Contract grant number: P30 ES01247.

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Accepted 30 July 1999

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evaluated, careful consideration of available control technologies should be initiated. The occupational hygiene community promotes adherence to a hierarchy of controls, described by the Occupational Safety and Health Administration (OSHA) in the Respiratory Protection Standard [OSHA, 29 CFR 1910.134, 1998] and by the American Thoracic Society (ATS) [ATS, 1996]. Both OSHA and the ATS prioritize the use of engineering controls before the implementation of work practice controls, administrative controls, or personal protective equipment. When engineering controls are not feasible as they do not sufficiently reduce exposure, or are not yet installed, employers can rely on work practice controls, worker rotation, or respirators. In many cases, a combination of controls is necessary to adequately protect workers. However, worker rotation and respirators are adjuncts to engineering and work practice controls, and should never be introduced as a primary measure.

The goal of engineering controls is to prevent exposure in the first place. The work is changed at the point of contaminant generation so that worker exposure is eliminated or substantially reduced. Common engineering approaches include substituting safer materials or operations for more hazardous ones, modifying processes or equipment, installing local exhaust ventilation, or isolating hazardous operations from workplace breathing zones. The most successful use of engineering controls occurs when designers incorporate worker protection measures at the planning stages for new operations. However, engineering ingenuity, when supported by industry, can lead to feasible and effective solutions even on older equipment and operations.

Work practice controls reduce exposure by adding protective procedures to high risk activities. These controls often rely on readily available materials and methods, but require careful implementation and management. Routine work practices to control airborne exposures include: wet methods for dust suppression, decontamination of the work area, and removal of hazardous material, such as lead-based paint or asbestos, prior to performing activities which could disturb these materials.

Administrative controls, such as worker rotation, are designed to restrict the time that workers are exposed to hazardous substances. This is a weak control method because it does not reduce contaminant emissions and requires strict adherence to work schedules and coordination with other controls. When this method is used, work assignments and time limits must be clearly defined and followed.

Finally, if the methods discussed above prove insufficient or infeasible, respirators and other protective equipment may be introduced either as the sole protective measure or in combination with other measures. In either case, implementation of an effective respiratory protection program is crucial. A recently published paper [Harber et al., 1999] describes the results of a very elegant decision model for optimizing respirator protection. The authors of this article conclude that the respiratory protection program plays a pivotal role in optimizing workers' protection afforded by these devices.

Although respiratory protection is the last line of defense against worker exposure to inhalation hazards, the wearing of respiratory protective devices to reduce exposure to airborne contaminants is widespread in industry. OSHA estimates that 2.6 million workers depend on respirators to protect their health [OSHA, 1994]. OSHA generally permits the use of respirators for worker protection in certain situations: while a company is waiting for the installation of engineering controls, as a supplement to other controls that have failed to lower worker exposure sufficiently, during maintenance and emergency work, and when there are no feasible engineering or administrative controls available. Workers in construction, asbestos and lead abatement, hazardous waste, health care and other industries are often in these situations and must rely on respirators, because the nature of their industries presents obstacles to the implementation of engineering controls.

There are many limitations in using respirators to protect workers from toxic and oxygen deficient atmospheres. Employers can avoid errors in respirator selection and use, which may eventually harm the exposed workers, by committing adequate personnel and resources to the development of a respirator program. Employers who require respirators are required by OSHA to establish a comprehensive program to assure that respirators are properly selected, used, and maintained [OSHA, 1998]. However, the 1998 OSHA Respirator Standard allows individuals to use respirators voluntarily at work without requiring the employer to institute such a program. Nevertheless, if the employee chooses to wear a respirator other than a dust mask, the employer must provide the employee with a medical evaluation and information on proper use of the respirator.

In 1998, OSHA revised the standard for respiratory protection [OSHA, 1998] which applies to workplaces in general industry, construction, shipyard, and maritime sectors. There is extensive information on the elements of respirator programs available to employers from government, professional, community, and health organizations (OSHA; National Institute for Safety and Health, NIOSH; American Industrial Hygiene Association, AIHA; American National Standards Institute, ANSI; National Safety Council, NSC). An acceptable program requires that the employer assign a responsible person to administer it and to describe responsibilities of all personnel engaged in the operation of the program. Daily monitoring is extremely important to assure that the goals of the respirator program are being met.

Respiratory Protection Program

An effective respiratory protection program includes both employer and worker responsibilities. The employer determines the wearer's exposures to hazards and selects an appropriate respirator for each task. The employer provides all wearers with a medical evaluation, training about the hazards, uses and limitations of respirators, as well as with fit testing, before use. The purpose of fit testing is to assure that workers using tight-fitting facepiece respirators are able to achieve a good face seal prior to initial use of the respirator. The employer must arrange for fit testing for all workers who are assigned tight fitting respirators before they are worn in contaminated areas, and annually thereafter. Fit testing is also repeated if the worker, the physician, or supervisor notices physical changes that might interfere with an effective face fit, such as surgery, facial scarring, or obvious weight change. Fit testing procedures include selection of a respirator face piece style and size, wearer instruction on donning, checking the face piece seal, and the use of an OSHA-accepted protocol [OSHA, 1998, Appendix A] for qualitative (exposure to irritant smoke, saccharin, isoamyl acetate, or Bitrex) or quantitative fit testing. Fit testing is also to be repeated if a worker notifies the supervisor or the physician that the fit of the respirator is unacceptable. Finally, the employer conducts inspections to determine if respirators being employed are in good condition and worn properly.

It is the worker's responsibility to comply with instructions learned through a formal education program on the use of respirators. The worker checks the face piece seal before each use (i.e., performs a user seal check each time he or she puts on the respirator), uses the respirator as instructed, guards against damage to it, reports malfunctions, turns it in for cleaning, and goes to an area with respirable air if the respirator fails to provide protection. The process of user seal check should be performed each time a tight fitting respirator is put on, to ensure that it is being worn properly. First, a positive pressure check is done by sealing off the exhalation port of the respirator while breathing gently into the mask. If a slight positive pressure is built up inside the facepiece without outward leakage, the face fit is considered to be satisfactory. Next, a negative pressure check is performed by sealing off the inhalation ports (air purifying cartridge or canister) and taking a breath and holding it for ten seconds so that the facepiece collapses slightly. The face fit is satisfactory if a slightly negative pressure is maintained without noticeable leaks into the respirator.

According to the new OSHA regulation, employers who require respirator use for worker protection must develop and implement a written site-specific respiratory protection program. Primary elements of the program must include [ATS, 1996; OSHA, 1998; Saphire, 1996]:

- Trained and qualified program administrator
- Procedures for selecting respirators based on evaluation of respiratory hazards, and workplace and user factors
- Medical evaluation of workers who must use respirators, based on the OSHA questionnaire [OSHA, 1998, Appendix C] and follow-up medical examinations as required
- Fit testing procedures for tight fitting respirators before respirators are worn and annually thereafter
- Use procedures for both routine and emergency situations
- Maintenance schedules and procedures including cleaning, disinfecting, storing, inspecting, repairing, and discarding
- Procedures to ensure that SCBAs and supplied air respirators have adequate air quality, quantity, and flow
- Worker training, at least annually, on the potential exposures to inhalation hazards and on respirator use including donning and removal, user seal checks (fit checks), limitations of respirators, and maintenance
- Procedures for evaluating program effectiveness
- Maintaining records of medical evaluations for at least 30 years, current fit testing, and the current respirator program.

The employer must provide all respirators, medical evaluations, and training at no cost to workers. For workers who voluntarily use respirators other than disposable dust masks, the employer must also provide medical evaluations and ensure that the respirators are properly maintained, cleaned, and stored.

Medical certification of respirator users is a required component of a respirator program. The revised OSHA standard includes a medical questionnaire, however, there is little guidance for employers, private physicians, and other providers to formulate adequate medical review of the physiological and psychological stresses of wearing respiratory devices.

Role of the Occupational Medicine Physician

Until February 1995, the American National Standard for Respiratory Protection, Respirator Use, Physical Qualifications for Personnel, ANSI Z88.6 [1984] was the only comprehensive document advising physicians and other professionals on medical examinations for respirator wearers. This document was withdrawn by ANSI in 1995 and has not yet been replaced by a new standard. OSHA recently issued a revised Respiratory Protection Standard [OSHA, 1998]. This new standard expands the role of the medical professional to evaluation of every worker prior to fit testing and initial use of a respirator, and providing

additional medical evaluation to respirator users when required by the employer, the worker, the supervisor or the respirator program administrator, or when changes in the conditions of the respiratory protective equipment or the workplace so require. Medical certification may now be performed by a physician or a licensed health care professional. The certifying health care professional must be informed by the employer of the job requirements and the respirator features for which certification is sought.

The purpose of medical certification of respirator wearers is to ensure that an individual can wear a respirator without causing physical impairment to him or herself and that wearing the respirator will not impede the safe performance of work duties. The occupational physician should always remember that, in dealing with medical certification for respirator wearers, he or she must be part of a team composed of industrial hygienists/safety representatives, employers, and workers.

The occupational physician can then play a central role in assuring that the respiratory protection program functions as a whole. These tasks include:

1. Assess fitness for work as a primary step when considering which worker is able to wear personal protective equipment (PPE). In order to achieve this, the physician must use personal judgment particularly regarding workers with underlying acute and/or chronic diseases [ATS, 1996].

2. Once this step is accomplished, the physician must identify which workers require medical certification. This requires cooperation from the employer and should not only cover workers who are exposed, but also workers in training and nonworkers such as outside inspectors, contractors, visitors, and others [ATS, 1996]. Although some workers may be in a medical surveillance program related to the kind of work they do (e.g., workers exposed to lead, asbestos, hazardous waste, firefighters), the physician must remember that the respirator certification may be the only time that the worker comes into contact with a medical professional. Therefore, appropriate evaluation with a general clinical history and physical examination for detection of previously undiagnosed medical problems should be done at this time, and appropriate referral recommended. The occupational medicine physician has the responsibility toward his or her patient to use this medical exam as a tool for prevention/education of the worker. Finally, the physician should use the medical visit to emphasize the importance of hazard control practices and reinforce the need for preventive and protective measures, proper use, fit, and selection of respirators. Respirator certification exams can be combined with surveillance exams or with preplacement, or annual exams if provided.

3. In order to provide medical certification for respirator wearers, physicians and other providers need information about workplace exposures including duration and frequency of respirator use, physical work efforts, other protective personal equipment in use, workplace temperature and humidity, toxic atmospheres and oxygen deficiency, selected respirators, work tasks, and applicable regulations. This information is supplied by the employer, as discussed below.

4. It is recommended that the physician participate with other professionals involved in the respiratory protection program, in periodically assessing and evaluating the program as a whole.

5. OSHA's revised standard extends the duties of the physician to discuss with the worker the questionnaire and examination results if so requested by the worker; to request a change in the respirator if there is any medical condition that may place the worker's health at increased risk with the proposed respirator to be used; to request additional fit testing or medical reevaluation if so considered by the physician when detecting changes in the worker's physical condition that could affect respirator fit, as well as when notified by the worker that the respirator fit is no longer acceptable.

DESCRIPTION AND SELECTION OF RESPIRATORS

NIOSH is responsible for classifying and certifying respirators for general and specific uses [NIOSH, 1991]. NIOSH's approval includes respirator components, such as facepiece, straps, harnesses, filters, chemical cartridges, regulators, air hoses, and connectors. NIOSH also recommends a protocol for selecting respirators based on the properties of the contaminant(s) and on the limitations of respirators [NIOSH, 1987] (Fig. 1). All respirators used to protect workers must be NIOSH approved or otherwise accepted by OSHA.

When worn properly, respirators cover the wearer's nose and mouth (inlet covering). Facepieces are either tight-fitting or loose-fitting. Tight fitting facepieces form a seal with the wearer's face and must be fit-tested to be sure that there is no leakage into the face mask. Loose-fitting facepieces cover all or part of the head without sealing directly onto the face. Tight fitting facepieces include:

1. Quarter masks, which cover the mouth and nose, and where the lower sealing surface rests between the chin and the mouth.
2. Half masks, which fit over the nose and under the chin.
3. Full facepiece, which covers from the hairline to below the chin.

Mask type (inlet covering), size, and facepiece design are major determinants of the leakage that occurs at the mask's facial seal surface and the protection factor afforded by the respirator. Full face masks are the most protective.

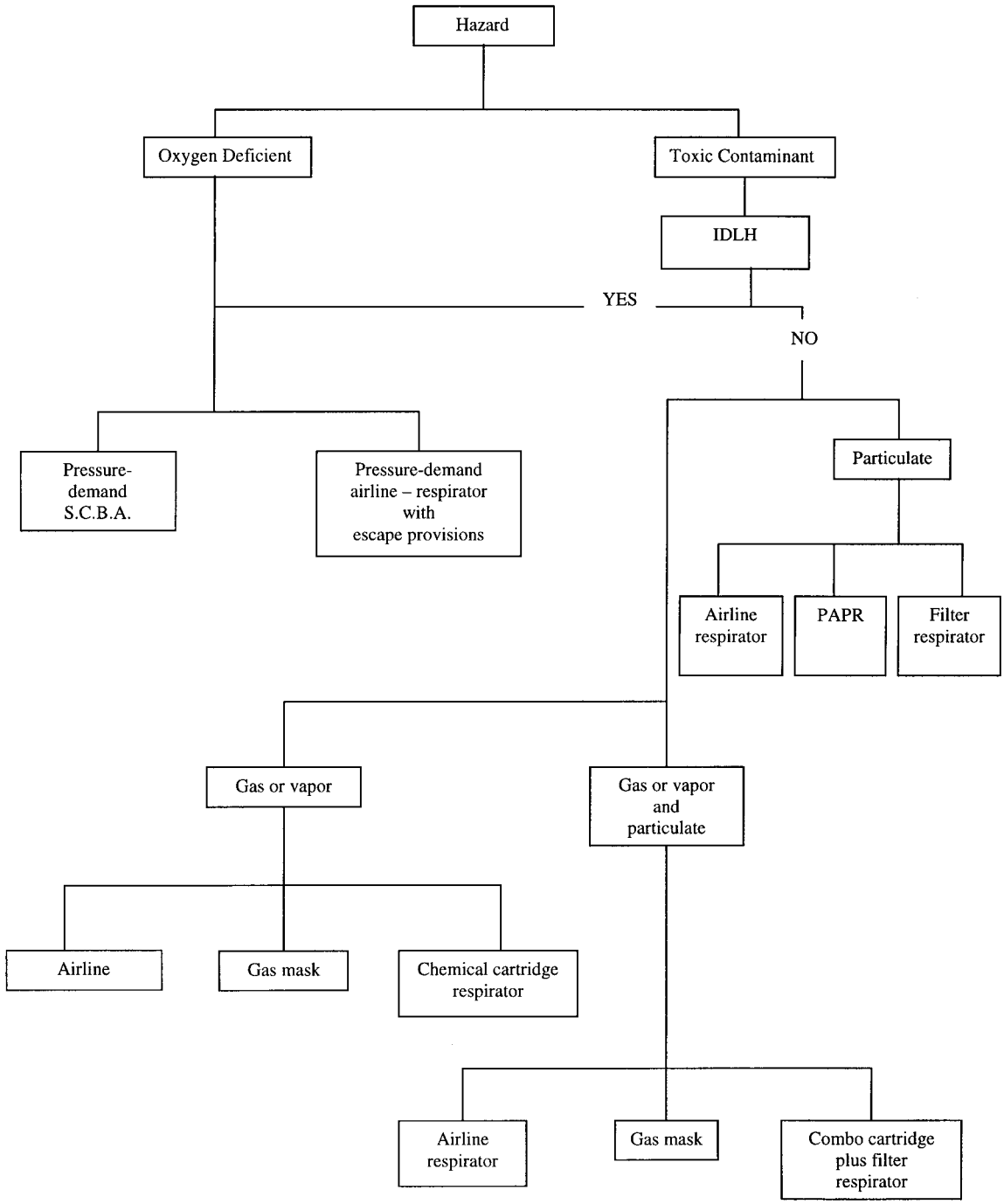

FIGURE 1. Respiratory Selection for Routine Use of Respirators. Adapted from: Occupational Safety and Health Administration. OSHA Industrial Hygiene Technical Manual. OSHA Instruction CPC 2-2-20A. Washington, DC.: US Government Office, 1984. IDLH: Immediately dangerous to life and health; PAPR: powered air purifying respirator; SCBA: self-contained breathing apparatus.

Loose-fitting facepieces include hoods, helmets, blouses, or full suits which cover the head completely. Respirators of this type do not require a tight facial seal but rather depend on airflow which generates positive pressure within the facepiece relative to ambient pressure to limit inhalation of toxic agents.

A small number of respirators used for very brief periods during emergency escape require that the user employs a nose clip and a mouthpiece attached to an air purifying cleaner.

Respirators are classified into two broad categories (Fig. 2):

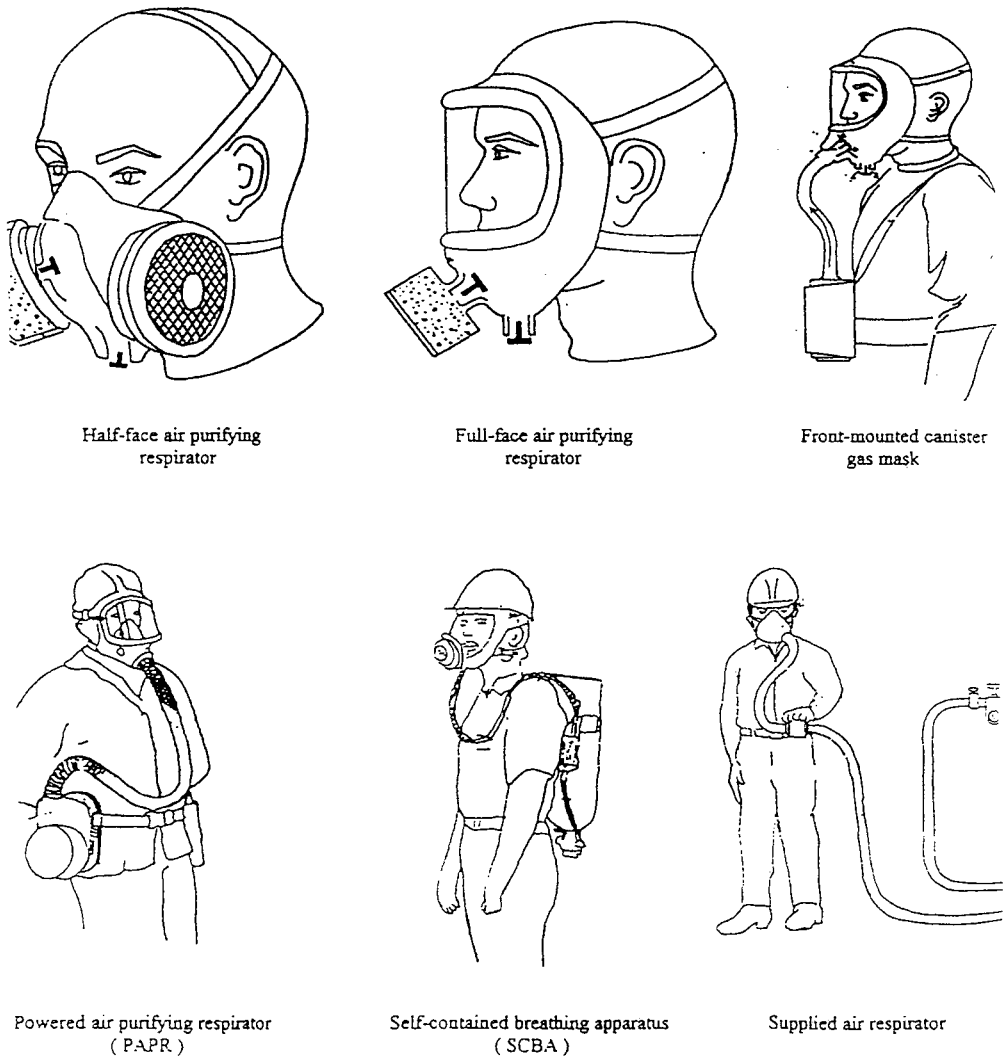

FIGURE 2. Types of Respirators. The sketches shown were taken from the NIOSH "Guide to industrial respiratory protection" (1987) and NJDOH, Powered air purifying respirators: Better protection from dust and fume" (1990).

1. Air-purifying respirators (devices which remove contaminants from the air by filtration, adsorption, or absorption)
2. Atmosphere-supplying respirators (also called air supplied respirators, those which provide clean breathing air from an uncontaminated source).

Air-Purifying Respirators

Air-purifying respirators are the most commonly used. They are grouped into three general types: particulate removing, vapor and gas removing, and combination. Elements which remove particulates are called filters, while vapor and gas removing elements are called either chemical cartridges or canisters. Filters and canisters/cartridges are the functional portions of air-purifying respirators, and they can generally be removed and replaced once their life has expired. The exceptions would be disposable respirators, those which cannot be cleaned and disinfected or re-supplied with an unused filter after use. Combination elements that protect from both particulate and vapors and gases are also available.

Filters and/or chemical cartridges attached to the respirator facepiece remove contaminants from the air during inhalation. A major disadvantage of these respirators is the creation of a slight vacuum or ''negative pressure'' inside the facepiece during inhalation. This negative pressure can cause contaminants to leak into the facepiece if it is not fitted properly. Powered air-purifying respirators diminish the possibility of negative pressure by blowing air through the filters or cartridges into the facepiece with a motorized fan. These respirators may offer more comfort to wearers by supplying a cool airflow into the mask and by reducing breathing effort.

Air-purifying respirators may be preferred because they are light weight and relatively easy to use. There are several serious limitations of these respirators that should be considered before they are selected:

1. Air-purifying respirators do not supply breathing air and cannot be used in oxygen deficient or potentially flammable atmospheres.
2. There must be an appropriate, NIOSH approved, filter or chemical cartridge for the contaminant of concern. Contaminant exposures cannot exceed the maximum use concentration determined by NIOSH for each chemical cartridge.
3. The 1998 OSHA Respirator Standard requires that programs using air purifying respirators have an end-of-service-life indicator cartridge or an appropriate change schedule for air purifying elements. The best time to change the filter or chemical cartridge is before there is contaminant breakthrough. Filters should be changed if they become contaminated, damaged or if it becomes difficult to breathe through. Chemical cartridges or canisters should be changed before breakthrough is detected by odor, irritation, or taste. Employees should refer to the NIOSH approval label and the manufacturers' recommendations for service life limitations.
4. Air-purifying respirators should not be used under conditions when the concentration of the contaminants is not known or cannot be reasonably estimated [OSHA, 1998].
5. Air-purifying respirators should not be used to enter an atmosphere immediately dangerous to life or health (IDLH).

Atmosphere-Supplying Respirators

Air-supplying respirators provide air from an outside source independent of the surrounding atmosphere, instead of removing contaminants from the atmosphere. Most air-supplying respirators use air from compressors or pressurized tanks. Air may be delivered through an airline from a remote source or carried on the wearer's back. Workers who are exposed to high levels of contaminants, oxygen deficient or flammable atmospheres, or to emergency conditions, are assigned to wear these respirators. Air-supplying respirators generally offer a higher level of protection. However, limitations of their use include:

1. Supplied air must meet quality specifications and be protected from contamination sources such as carbon monoxide from combustion sources.
2. Self-contained breathing apparatus (SCBA), composed of facepiece, hose, regulator, tank and harness, and low-air alarm, generally supply a very limited amount of air (often less than 30 minutes).
3. Air-supplying respirators, composed of facepiece, regulator, air hose and pressurized air source, must be used in an approved combination to ensure adequate air supply to the wearer.
4. Air-supplying respirators may burden the wearer with excessive weight (up to 35 lb for SCBAs) and cumbersome hoses and attachments.
5. Airflow into the respirator facepiece may get dry causing irritation in the eyes and mucous membranes.
6. Only SCBAs or air-supplying respirators with SCBAs can be used in case of a hazard posing immediate danger to life or in oxygen deficiency circumstances.

Substance-Specific OSHA Requirements

The revised OSHA Respirator Standard [OSHA, 1998] applies uniformly to all regulated substances and updates the respirator program requirements of the substance-specific standards to include elements of the new Respirator Program. The substance-specific standards, however, retain their individual medical evaluation and respirator selection requirements (Table I). Other requirements, such as, written program, training, fit testing, and use of respirator, are now the same for all substances.

The old respirator standard, renumbered 1910.139, has been retained for protection against exposure to tuberculosis. OSHA intends to issue a standard for tuberculosis in the near future and the new Respirator Standard will be incorporated into the tuberculosis standard at that time.

TABLE I. OSHA Substance-Specific Regulations

Substance	OSHA Standard
Asbestos	1910.1001, 1926.1101
Vinyl chloride	1910.1017, 1926.1117
Benzene	1910.1028, 1926.1128
Cadmium	1910.1027, 1926.1127
Cotton dust	1910.1043
Formaldehyde	1910.1048, 1926.1148
Inorganic arsenic	1910.1018, 1926.1118
Coke oven emissions	1910.1029, 1926.1129
1,2 dibromo-3-chloropropane	1910.1044, 1926.1144
Acrylonitrile	1910.1045, 1926.1145
Ethylene-oxide	1910.1047, 1926.1147
Lead	1910.1025, 1926.62
Pulp, paper and paper board mills	1910.261
13 carcinogens	1910.1003, 1926.1103–04, 1106–1116
Methylenedianiline	1910.1050, 1926.60
1,3-butadiene	1910.1051
Methylene chloride	1910.1052, 1926

EFFECTS OF RESPIRATOR USE

Although the medical literature describes negative effects of respirator use, for most people who are fit to do the job, there usually is a respirator model to fit their needs. The physician, however, must be aware of the clinical problems related to respirator use in order to meet the personal needs of a particular worker. The physician determines whether a worker is to be medically approved to wear the respirator that the employer has selected. If not, the physician should recommend an alternative respirator (Table II).

Respiratory Effects

Attention to lung disease is perhaps the most important factor to consider when estimating the effects of respirators. As previously stated, the issue of fitness for work should take priority over the decision of respirator certification. Specifically, in dealing with respiratory conditions and respirator certification, it is important to consider factors as broad as the severity of asthma or the weight of SCBAs (up to 35 lb) in individuals with heart or lung disease. The following is a more detailed review of the respiratory effects of wearing respirators.

Increased airways resistance

The wearing of a negative pressure respirator increases the resistance to inspiration because of the increased resistance to air flow caused by the filter media and facepiece flow channels [Hermansen, et al., 1972; Harber, et al., 1989; Raven, et al., 1979]. The problem is reduced with powered air-purifying respirators and with positive pressure air-supplying respirators [ATS, 1996]. Exhalation resistance with modern negative pressure respirators does not significantly increase expiratory effort. As the inspiratory resistance increases, the inspiratory muscles (diaphragm and intercostal muscles) fatigue faster [Deno et al., 1981; Gee et al., 1968; Hermansen et al., 1972; Harber et al., 1989; Hodous, 1986; Raven et al., 1977, 1981b; Stemler and Craig, 1977].

There are studies in the medical literature showing that negative pressure respirators in normal subjects limit maximal aerobic exercise at high levels of exertion, and therefore reduce maximal work capacity [Arboelius et al., 1983; Bentley et al., 1973; Bjurstedt et al., 1979; Deno et al., 1981; Hodous, 1986; Raven, 1984; Raven et al., 1977, 1981a; Stemler and Craig, 1977].

The respiratory protective equipment may add to the work of breathing and (in the case of heavy equipment) skeletal muscle work, leading to earlier dyspnea and fatigue for a given sub-maximal exercise task, and to reduced maximal work capacity [Craig et al., 1970; Deno et al., 1981; Raven et al., 1977; Stemler and Craig, 1977; Wilson et al., 1989a, b]. This may hasten or make worse respiratory muscle fatigue when the person wearing a respirator is affected by severe chronic airways obstruction, severe emphysema, asthma (in some cases), and moderate to severe interstitial lung diseases, as well as by clinically significant heart disease.

For those with a history of pneumothorax, there is at least a theoretical hazard associated with increased swings in pleural pressure which should be considered when performing respirator certification [Hodous, 1986].

Wearers of particulate air-purifying respirators may detect an increase in breathing resistance as the filter becomes loaded. The physician should remind the worker to request a filter or chemical cartridge change whenever he or she perceives any increase in breathing resistance, or notes irritation, odor, or taste of contaminants.

Increased dead space volume

Wearing a respirator mask adds to the dead space volume [Raven, 1984; Hodous, 1986a]. This dead air space added to the anatomic dead air space, requires the wearer to increase the depth and frequency of breathing to obtain the same amount of fresh air. The response to increased dead space is increased respiratory rate and tidal volume, and consequent increased work of breathing. An alternative to reducing dead space in a full mask respirator is the insertion of nose cups within the mask. These are often a standard component of full face respirators. Clinical studies have shown, however, that increased resistance and dead space can lead to very mild decreases (by approximately 10%) in maximal work performance [ATS, 1996; Craig et al., 1970; Deno et al., 1981; Morgan, 1983; Raven et al., 1977; Stemler and Crag, 1977].

Studies in groups of individuals with moderate obstructive pulmonary disease or restrictive pulmonary impairment, have found no difference in their graded exercise performance with or without a respirator [Altose et al., 1977; Bentley et al., 1973; Hodous et al., 1983; Love et al., 1977; Raven et al., 1982; Hodous et al., 1986]. Thus while using a respirator, such individuals should not suffer from an added strain. To date, there is no scientific basis for using a certain level of lung function as a "cut off" to predict which individuals can and which cannot successfully use a respirator in the workplace. It should be noted, however, that these are studies of small groups of individuals, and, as always in medicine, personal consideration should be given to any patient when examining his or her particular case [Raven, 1984; Hodous, 1986].

Cough

A respirator might add to the burden of a person who suffers from chronic or acute cough condition. An

TABLE II. Summary of Effects of Three Types of Respirators on the Worker

Type of respirator	Respiratory	Cardio-vascular	Discomfort	Ergonomics	Psychosocial	Skin	Senses
Air-purifying (negative pressure)	Little breathing resistance; difficulty in cough; full-face mask; increased dead space	Few effects	Thermal load; tightness; pain	Few effects	Yes	Yes	Speech communication difficult; smell interference; full-face mask may interfere with vision
Powered air purifying (continuous flow)	Little breathing resistance; cough difficulty	Few effects; some models add load	Thermal load (less than negative pressure models); tightness; pain	Few effects; some models add load to face mask and belt	Yes	Yes, for tight fitting mask	Speech communication difficult; air flow sound may interfere with hearing; smell interference; full-face mask may interfere with vision
Air line:compressor or tanks	Cough difficulty; demand regulator (negative pressure) may increase breathing resistance; full-face mask increase dead space	Few effects	Thermal load (less than negative pressure models); tightness; pain	Air hose may be cumbersome and heavy	Yes	Yes, for tight fitting mask	Speech communication difficult; air flow sound may interfere with hearing; smell interference; full-face mask may interfere with vision
SCBA	Cough difficulty; full-face mask increases dead space	Yes, heavy load	Thermal load (less than negative pressure models); tightness; pain	Unit adds weight and volume to user	Yes	Yes, for tight fitting mask	Speech communication difficult; air flow sound may interfere with hearing; smell interference; full-face mask may interfere with vision

individual with a productive cough would need to remove the mask to get rid of the sputum. Also, coughing action might create enough pressure to break the seal of the mask on the face. In the opinion of the authors, a chronic or acute cough condition, if permanent, should be considered as a contraindication for worker's certification.

Cardiovascular Effects

Wearing SCBA respirators can increase cardiac work load (due to the weight carried), whereas a negative pressure respirator, if well maintained, would not significantly increase it [Gee et al., 1968]. Heavy respirators such as SCBA, may increase the heart rate by about 20% at submaximal physical activity [Raven et al., 1977], and reduce the maximum exertion level by the same amount. Although in healthy young people, the increase in percentage of O_2 consumption from the respiratory muscles caused by using a respirator (3–6%) is considered negligible [Gee et al., 1968; Hodous et al., 1983], in individuals with significant cardiac or pulmonary disease this should be taken into consideration. In addition, the increased cardiac workload could be enhanced by temperature-conservation with impermeable protective clothing used in warm weather [Hodous, 1986]. Concerns that positive pressure respirators might cause some decrease in the cardiac output have been shown not to be of clinical relevance [Arboelius et al., 1983; Bjurstedt et al., 1979; Hodous et al., 1983, 1986; Raven, 1984; Raven et al., 1982].

Some studies show that women and men over the age of 50 years consume more oxygen than a younger male in order to perform the same task [Bink, 1962]. This should also be taken into account when examining patients for respirator certification.

Discomfort

Significant thermal discomfort should be expected when wearing respirators, even half-face tight-sealed masks or paper/fabric respirators such as the ones used for TB, as the tight fit of the mask over the face causes a build up of moist warm air inside the facepiece [DuBois et al., 1990; Nielsen et al., 1987; Zelnick et al., 1994]. This effect is exaggerated when protective clothing is being used [Arboelius et al., 1983; Hodous et al., 1983; James et al., 1984]. Powered air-purifying respirators or respirators with exhalation valves are often considerably more comfortable.

Workers who require both respirators and protective clothing should have frequent opportunities to cool-off or doff the equipment [ATS, 1996]. Closed circuit SCBA breathing units have the potential for heat stress because warm expired gases (after CO_2 removal and O_2 addition) are re-breathed [Hodous, 1986; James et al., 1984].

Pain is sometimes experienced especially from tightly fit respirators and after prolonged use. The elastic head straps of the respirator required for an air tight fit may impede lymphatic flow in the face, causing headaches and facial pain.

Extra Weight and Ergonomic Concerns

Self-contained breathing apparatuses may add up to 35 lb of weight to the worker. Neck and back muscles carry this additional weight, and fatigue can result. Some powered air-purifying respirators also add the weight of the battery-powered pump to the belt. Because of the added weight-load, particular attention should be given to conditions such as herniated disks, and other chronic musculoskeletal ailments. It is important to instruct the worker on the need for the harnesses to be properly adjusted and worn.

Respiratory equipment unnaturally ''enlarges'' the worker. He or she must use caution when climbing or walking through tight spaces, looking through view ports, or handling bulky equipment. Wearing SCBAs can prevent passage through narrow spaces and hatches.

Psychological and Social Effects

Psychological effects while wearing respirators vary from mild discomfort to real inability to tolerate the mask and anxiety [Morgan, 1983; ATS, 1996]. Difficulty in tolerating the mask may even give rise to the subjective feeling of breathing difficulty. Disqualification for psychological reasons constitutes approximately 10% of the medical disqualification. Experience with the use of respirators might aid in reducing intolerance. Fit testing and experimenting with different respirator models might help as well [Harber et al., 1991; Hodous, 1986].

Wearing a respirator in general does not affect the speed or accuracy of the worker when performing tasks. However, it has been shown that wearing respirators when performing tasks for high quality products (e.g., inspection of printed circuit boards) resulted in longer response times and higher miss rates [Jaraiedi, 1994].

Various clinical studies show that acceptability to workers is a significant factor that limits the ability of respirators to provide protection against inhalation hazards [Aucoin, 1975]. The discomfort arises from various factors: increased temperature inside the mask, pressure on the face due to the respirator's elastic straps, perception of inspiratory resistance, the feeling of being enclosed, effects on vision and on hearing [ATS, 1996]. Discomfort may result in reduction of the fractional protection factor offered by the respirator as the worker may dislocate the mask and/or use it in a non-appropriate position. Studies have shown that removing the respirator even for a short period of time (i.e., 10%) can result in excessive exposure [3M, 1983].

Skin Problems

Workers may develop local skin diseases and allergic reaction when wearing respirators. Skin occlusion may exacerbate pre-existing conditions. Men with Pseudofolliculitis barbae cannot shave closely because it makes the condition worse, and thus must be fitted with loose-fitting models [Hodous, 1986]. Facial anatomical abnormalities or the presence of a beard or a mustache can affect the respiratory face seal if they extend to sealing surfaces.

Senses

The use of a respirator decreases visual fields because of the respirator edges [Kraut, 1988]. It also reduces hearing, voice clarity/loudness, communication, and sense of smell [Morgan, 1983].

Hard contact lenses are not recommended for use with respirators. A dislodged contact lens secondary to rubbing an irritated eye or caused by air pressure from a positive pressure or air supplied respirator could decrease vision and put the individual at risk [Hodous, 1986]. However, use of gas permeable and soft contact lenses in all work places and with all types of respirators was accepted by OSHA [US DOL, 1988]. OSHA's new Respirator Standard simply allows contact lenses without any special restrictions [OSHA, 1998]. The worker should be instructed in contact lenses use, the symptoms associated with their malfunction, and the importance of seeking immediate help if an injury occurs. Workers who need to wear eyeglasses under full face masks must have prescription glasses made which can be mounted inside the facepiece, since the temple bars will break the face seal.

Perforation of the tympanic membrane is not a contra-indication to respirator use. There is no inspiratory air flow down the eustachian tube, so this does not represent an alternate route of inhalation. The ability to hear and to respond to emergency alarms or warning devices may be impaired when wearing an airline respirator with a hood or helmet that covers the head.

Pregnancy

Although at present there are no good data on respirator use in pregnancy, a recent study found that pregnancy was the most common cause for denying medical clearance for respirator use [Pappas et al., 1999]. The new OSHA Respirator Standard does not include pregnancy in its mandatory questionnaire. When deciding on respirator use in pregnancy, the physician should base his/her conclusions on consideration of the risks of the work-environment to the mother and to the developing child (remembering that protective equipment may fail or may give incomplete protection), the capability of the mother to tolerate the protective equipment required [Pappas et al., 1999], as well as on ergonomic considerations regarding the pregnant condition of the mother.

WORK CONDITIONS

There are a variety of factors in the workplace which can add to the psychological and physical stress of the individual wearing a respirator. These factors should also be accounted for when examining workers for respirator certification, because they represent additional energy expenditures which the worker has to afford when performing his or her work-tasks [Kraut, 1988; Louhevaara, 1984; Raven et al., 1979]. Some of these conditions can be summarized as follows:

Job characteristics
- Heavy workloads requiring oxygen consumption of more than 1.3 L/min
- Long work duration and irregular rest periods

Work environment
- Heat stress
- High contaminant air concentration
- Environment hazardous to life
- Noise, confined spaces

Psychological stresses
- Time pressure
- Contract work (i.e., piece work)
- Night or rotating shift work

Equipment-related stresses
- Characteristics and type of personal protective equipment
- Amounts of time the respirator/other personal protective equipment must be worn
- Impermeable protective work clothing

WORKER EVALUATION

The respirator use evaluation may be the only physical examination the worker has had for some time. The physician should be aware of this opportunity to detect other previously undiagnosed medical conditions that could jeopardize the general health of the worker, and to conduct education focused on disease prevention.

Work Description

Prior to the medical evaluation for respirator certification, the employer should provide the examining physician with information concerning:

1. The type and weight of respiratory protection to be used;
2. The substances to which the worker will be exposed;

3. Description of the work effort required (terms such as light, moderate, heavy or strenuous, and sustained effort, should be used);
4. Duration and frequency of usage, defined in one of three ways:
   a. On a daily basis (if so, how many hours a day)
   b. Occasionally, but probably more than once a week
   c. Rarely or for emergency situations only;
5. The type of work performed, including any special responsibilities that affect the safety of others such as fire fighting or rescue work;
6. Any special environmental conditions such as temperature and humidity extremes, or confined space entry;
7. Additional requirements for protective clothing and equipment; and
8. A copy of the written respiratory protection program and of the OSHA revised respirator standard.

It is therefore very important that medical office personnel or the people making arrangements with the employer make sure this information is available prior to medical examination. The physician needs to know about the different type of respirators, the effects of wearing respirators, the exposure and the selected respirator, how long and how often will the device be worn, the work effort required, and the warning properties (end of service life indicator) of the respirator in order to make a proper judgment of fitness.

Medical History and Physical Examination

The physician's evaluation of suitability of the individual examined for respirator use should be based on perception of the work ability of the individual and not based specifically on a diagnosis. It is the role of the physician to determine whether the individual is fit for the work itself, and then if the individual is able to wear a respirator in that job.

A medical history such as the OSHA questionnaire [OSHA, 1998; Appendix A] can be utilized to identify the following:

1. Previously diagnosed disease, particularly stressing known cardiovascular or respiratory diseases;
2. Psychological problems or symptoms including claustrophobia;
3. Problems associated with breathing during normal work activities;
4. Visual or auditory impairments, including color vision assessment;
5. Past problems with respirator use or worker concerns about the proposed use of respiratory protective devices;
6. Current usage of medication, especially current use of medications whose side effects might impact the cardiopulmonary or CNS system, or their ability to make appropriate decisions related to their own safety or the safety of others, including current use of alcohol;
7. Any known physical deformities or abnormalities, including disc herniation and other musculoskeletal and radicular symptoms that may interfere with respirator use;
8. Heat intolerance;
9. Previous occupations and use of respirators.

The following conditions should be assessed during physical examination:

1. Musculoskeletal condition and anatomical problems (especially for SCBAs);
2. Facial deformities and facial hair;
3. Use of prescription eyeglasses or contact lenses;
4. Hearing ability (should be sufficient to ensure communication and response to instructions and alarm systems);
5. Significant restrictive or obstructive respiratory diseases or significant diffusion disorders of the lung;
6. Cardiovascular diseases: evidence of symptomatic coronary artery disease, significant untreated arrhythmias, or history of recent myocardial infraction, uncontrolled hypertension or related symptoms;
7. Endocrine disorders: conditions which may result in sudden loss of consciousness or response capability (i.e., poorly controlled insulin-dependent diabetes);
8. Neurological disability: inability to perform coordinated movements and conditions affecting response and consciousness; history of uncontrolled epilepsy;
9. Psychological condition: claustrophobia, severe anxiety;
10. Other conditions specific to the work situation such as skin conditions where occlusive materials may result in symptoms or aggravation of a pre-existing dermatitis.

In an individual who has a history of not tolerating a respirator in the past, the medical examination should be more focused upon the reasons why the individual did not tolerate the respirator in addition to the general examination guidelines previously described. According to the revised OSHA standard for respirator certification, any worker should have a physical examination if he or she:

1. Is a current tobacco smoker, or has smoked tobacco during the month prior to the medical evaluation;
2. Has any history of seizures, diabetes, respiratory allergic reactions, claustrophobia, difficulty in smelling odors;

3. Has any history of asbestosis, asthma, chronic bronchitis, emphysema, pneumonia, tuberculosis, silicosis, pneumothorax, lung cancer, broken ribs, any chest injury or surgery or any previous lung problem; or any lung symptoms such as shortness of breath, coughing, wheezing, or chest pain;
4. Has any history of heart attack, stroke, angina, heart failure, lower extremity edema, arrhythmia, high blood pressure or any other heart problem; or heart symptoms such as chest pain or tightness, missing heart beat, or heartburn unrelated to eating;
5. History of any medication for breathing or lung problems, heart disease, blood pressure, or seizures; and,
6. History of any previous difficulties using a respirator (eye irritation, skin allergies, general weakness or fatigue).

In addition to the medical questionnaire proposed in the revised OSHA standard for respirator use, the physician is entitled to request any other information he or she may consider necessary. The physician is also required to recommend additional fit testing when detecting changes in the worker's physical condition that could affect respirator fit (i.e., facial scarring, dental changes, cosmetic surgery or an obvious change in body weight), or if notified by the worker that the fit of the respirator is no longer acceptable. If medically indicated, a powered air purifying respirator can be recommended by the physician to replace a negative pressure respirator.

Special Testing

Pulmonary function tests

These should be performed only to assist decision making for patients with lung disease [ATS, 1996]. There are special situations, however, during which performance of routine respiratory function tests is required, i.e., fire fighters' and asbestos workers' certification for respirator use. Spirometry for measuring FEV1 and FVC is the minimal recommended, in order to establish the presence and degree of restrictive or obstructive impairment.

Exercise stress test

A maximum exercise stress test with measurement of maximal oxygen consumption may be helpful to the examining physician who has questions about the overall work capacity of personnel who use SCBA [ATS, 1996] or rebreather-type respirators, especially if it is going to be used under strenuous work effort or in emergencies, particularly in fire and rescue operations. Individuals who have apparent ischemic disease or cannot perform well on a treadmill because of respiratory, musculoskeletal, or other physical problems, should not be assigned to use these devices. In general it should be remembered that a worker involved in manual labor who is more or less free to set the workpace can work comfortably at approximately 40% of his maximal aerobic capacity ($\dot{V}_{O_2}$max). Strenuous, heavy labor requires $\dot{V}_{O_2max}$ of 20–30 mL/kg/min. If 40% of the subject's oxygen consumption is greater than or equal to the average metabolic work requirement of his job, then the subject should be able to perform that job comfortably.

Chest X-rays

When an abnormality is discovered during the course of the evaluation, an x-ray may be helpful to further study the patient. Also, when x-ray is required legally, or needed to evaluate exposures or other medical conditions, then it can be included in the evaluation process. Most of the time there is no justification for taking a chest x-ray only for the purpose of respirator certification. The physician should not forget, however, that respirator use evaluation may be the only physical examination the worker has had for some time. Clinical judgment is recommended in each particular case.

Other tests

These may be indicated in special circumstances. Hearing and vision testing should be performed on potential rescue team members if these senses are critical to safety or job performance [ATS, 1996] (i.e., color blindness if using end of service life indicators).

Reevaluations

Previous guidelines had recommended periodic reevaluation to assess fitness to wear respirators [Hodous, 1986; Kilbom, 1980]. A more generally accepted current approach is to reevaluate only those workers who are having difficulties with respirators as soon as a difficulty is encountered. The revised OSHA standard does recommend periodic reevaluation for respirator fitness under the following conditions: when the worker gives a positive response to any question among questions 1 through 8 in Section 2, Part A of Appendix C of the current OSHA Standard [OSHA, 1998]; when the worker reports signs or symptoms that are relevant to the worker's ability to use a respirator; when the physician, supervisor, or respirator program administrator considers it necessary for the worker to be reevaluated; when information from the respirator program, including observations made during fit testing or program evaluations, indicates a need for worker reevaluation; or if a change in workplace conditions occurs that may result in a substantial increase in the physiological burden that respirator use places on the worker.

RECOMMENDED CRITERIA FOR CERTIFICATION

Based on the results of the overall evaluation, an individual can be either permitted full or restricted use respirators [Harber et al., 1984; Beckett, 1986; Kraut, 1988], as follows:

Full use

Individuals who are found fit to wear all types of respirators in all conditions, without limitations.

Restricted use

The restriction should apply to the type of respirator (SCBAs) or tasks performed (rigorous work while wearing a negative pressure respirator), as well as to the duration of tasks to be done (long work duration in strenuous environment). The physician can specify the type of respirator the worker could wear, as well as the type(s) of respirator(s) he or she should not be using. According to OSHA, for example, if the physician finds that a worker can't wear a negative pressure respirator because of skin problems, the employer should provide the worker with a loose fitting air-purifying respirator [OSHA, 1998]. Clinical judgment is needed to make a decision to certify a particular worker under the specific conditions of the work for which he or she is being certified.

Individuals who present special limitations for respirator use. Special clinical judgment is required when examining individuals who present with any of the following:

1. Severe cardiopulmonary disorders, especially current or recent ischemic heart disease; severe hypertension, unstable or uncontrolled; potentially life-threatening arrhythmias. Following an uncomplicated myocardial infarction with a negative stress test, the individual can usually return to a job demanding about seven metabolic equivalents (METS) (e.g., moving a pallet jacket). If an exercise test is available, please refer to Table III for further interpretation and grading of exercise test results (modified from Wilson and Raven [1989]). Individuals with asymptomatic coronary artery disease have performance capabilities of 7–10 METS (e.g., carrying 36 kg load, heavy machine assembly, sawing hardwood) [Saphire, 1996];
2. Severe, uncontrolled pulmonary impairment, defined by any of the following:
   a. Decreased FEV1/FVC actual (measured) ratio (<70%) *plus* an FEV1 of <50% of predicted;
   b. Normal FEV1/FVC actual (measured) ratio (≥70%) plus an FVC of <50% of predicted; or
   c. History of severe, unstable, and difficult-to-control asthma;
3. Previously demonstrated inability to tolerate a respirator may indicate inability to safely wear a respirator unless an acceptable model can be found;
4. OSHA requirements specifically restrict respirator use among workers who have beards, facial scars or deformities, and denture wear when such conditions interfere with the mask seal (i.e., the individual fails the fit-testing for respirator);
5. Use of contact lenses as previously noted;
6. Age of 60 years and above may make it more likely that a contraindicating medical or physical condition for doing the job is present;
7. Other major health problems that limit the person's ability to care for and deal with the respirator, as well as individuals who suffer from disorders that limit their ability to don or doff the respirator (i.e., severe arthritis, neuromuscular disease).

TABLE III. Work Load and Metabolic Equivalents

Work rating	Energy cost (O_2 uptake)		
	L/min	mL/kg/min	METs[a]
Light work	up to 0.5	5–7	1–2
Moderate work	0.5–1.0	15	2–4
Heavy work	1.0–1.5	20–30	4–6
Very heavy work	1.5–2.0	≥30	6–8
Extremely heavy work	2.0–3.0		8–12
Exhaustive work	>3.0		12–15

[a]One MET = 3.5 mL/kg/min V_{O_2}.
Modified from Wilson, JR, Raven PB. 1989a. Clinical pulmonary function tests as predictors of work performance during respirator wear. Am Ind Hyg Assoc J 50:51–57.

Reasonable accommodations according to the American with Disabilities Act. A reasonable accommodation of workplace requirements for individuals with medical and psychological disabilities is required under the Americans with Disabilities Act, and applies to respirator use as it does to other aspects of job requirements. This Act allows individuals to be disqualified for respirator use who have a bona fide inability to safely use any respirator, but requires "reasonable accommodations" where possible, which would probably include the employer providing an alternative respiratory protective device. Thus, an individual unable to obtain a good fit test for a negative pressure respirator due to facial scarring from a radical neck dissection might be able to achieve good protection with a loose-fitting positive pressure respirator. Here the expertise of an industrial hygienist familiar with all types of respirators can be extremely important.

CONCLUSION

Medical certification for respirators is a very important part of the activities of the occupational physician. It not only entails the ability to decide which worker is able to tolerate the added strain of a respiratory protective device (as a matter of fact, for most people able to do the job, there is usually a respirator model which will fit their needs). Rather, it should be viewed as a whole decision process where fitness for work, integration of intrinsic factors related to the health of the individual and of extrinsic factors related to the characteristics of the work itself, together with the properties, type and requirements of the respiratory protective device, should be combined. More importantly, however, medical certification for respirator use should be viewed as an element of a comprehensive respiratory protection program. This is the real key factor in affording workers' effective respiratory protection once the initial steps of the hierarchy of methods of hazard control have proven insufficient or infeasible. As a result, the need for the industrial hygiene/safety person, the worker, the employer and the medical professional to work as a team is much more than in any other field of occupational medicine, a basic requirement for making the right decision. Finally, as previously stated, the physician must remember that often this will be the only opportunity a worker comes in contact with a medical professional. Prevention, public health, education, and early detection of other medical conditions should always guide a respirator certification process.

ACKNOWLEDGMENT

This clinical practice review was based on an initial report submitted in 1990 to the New York State Department of Health by Dr. Wajdy L. Hailoo.

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